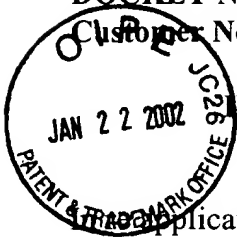


DOCKET NO. PRES06-00219

PATENT

Customer No. 23990



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#10

Application of : J.T. Lin
Serial No. : 09/820,830
Filed : March 30, 2001
Title : METHODS AND APPARATUS FOR PRESBYOPIA
CORRECTION USING ULTRAVIOLET AND
INFRARED LASERS

Commissioner for Patents
Washington, D. C. 20231

Sir:

PROTEST UNDER 37 C.F.R. § 1.291

Pursuant to 37 C.F.R. § 1.291, this protest is being filed against the above-identified application and the claims therein as published on October 11, 2001 in Publication No. US 2001/0029363 A1. A citation on Form PTO-1449 of prior art references relied upon is being concurrently filed, with copies of the references cited.

Pursuant to 37 C.F.R. § 1.248(b)(2), the undersigned hereby certifies that a copy of this paper and all attachments is being served under 37 C.F.R. § 1.248(a)(4) by transmission by first class mail to the correspondence address designated in the published application:

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02/19/2002 STHORNTD 00000005 500208 09820030
01 FC:216 200.00 CH

on the date of filing of this paper.

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The relevance of each item listed on the attached Form PTO-1449 is as follows:

Published claims 1-2, 4-10, 15 and 19-20 are potentially invalid under 35 U.S.C. § 101 for double-patenting over U.S. Patent Application Serial No. 09/794,496 ("the '496 application") and the claims therein as filed by the named inventor of the subject application on February 28, 2001 and published on August 23, 2001 in Publication No. US 2001/0016736 A1. Published claims 1-6 and 11-14 of the subject application are identical to published claims 1-2, 4-10 and 20 of the '496 application, with the claims corresponding as follows:

<u>'496</u>	<u>'832</u>	
1	1 ✓	
2	2 ✓	
3	4	OK
4	7	OK
5	5 ✓	
6	6 ~ OK	
11	8	OK
12	9	OK
13	10	OK
14	20 ~ OK	

Additionally, published claims 7, 8 and 9 of the subject application have similar scope to, although not identical language with, published claims 15, 20, and 19, respectively, of the '496 application.

Published independent claim 1 is anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,489,299 to *Schachar*. Published claim 1 recites only removal of scleral tissue in a predetermined pattern and area to increase accommodation in presbyopic eyes by movement

of the ciliary body and zonular fiber connected to the lens of the eye. *Schachar* '299 teaches that presbyopia may be corrected by increasing the effective working distance of the ciliary muscle either by movement of the ciliary muscle and the connection of the zonules to the ciliary muscle through scleral expansion or by shortening the zonules. *Schachar* '299, column 4, lines 34–59. *Schachar* '299 teaches such correction of presbyopia by expansion of the sclera--and attendant movement of the ciliary muscle and zonule connection thereto--will result from internal ocular pressure (IOP) when a laser is employed to weaken the sclera by removal of a portion of the scleral tissue:

If the sclera is weakened in the area adjacent to the ciliary body, the IOP will cause that portion of the sclera to bulge outward, The sclera may be thinned or weakened by the surgical removal of a portion of its collagenous substance, as, for example, by ablating a portion of the thickness of the sclera. This thinning can be accomplished by paring or by abrading the surface or by ablating the surface with laser irradiation.

Schachar '299, column 7, lines 32-34 and 54-59. *Schachar* '299 also teaches that virtually all lasers conventionally used for ocular surgery may be employed in weakening the sclera to cause expansion:

Suitable lasers include those conventionally used in ocular surgery such as carbon dioxide lasers, . . . holmium doped yttrium-aluminum garnet (YAG) lasers, excimer lasers, . . . and the like.

Schachar '299, column 8, lines 10–18. This teaching by *Schachar* '299 enables skilled artisans to practice the method recited in claim 1 since those skilled in the art are familiar with the use of various lasers in photoablation of ocular tissue. For example, U.S. Patent No. 5,144,630 to

Lin or U.S. Patent No. 5,520,679 to *Lin* (both issued to the named inventor of the subject application) document use of photoablative lasers to remove ocular tissue. (Protester notes that anticipation may be properly shown through multiple references when the extra references merely show that the primary reference contains an enabling disclosure. MPEP § 2131.01). In particular, *Lin* '679 extensively documents the considerations which would be employed by those in the art in selecting lasers for photoablation of ocular tissue, as well as corresponding equations employed to select laser wavelength and energy (intensity), spot size, pulse duration, scanning rate, etc. to achieve a desired ablation profile and/or ablation thickness per pulse. *Lin* '679, column 6, line 41 through column 8, line 6. Accordingly, those skilled in the art are enabled by the teachings of *Schachar* '299 to perform laser photoablation of scleral tissue to cause scleral expansion and attendant movement of the ciliary body and/or zonules without undue experimentation. *Schachar* thus fully anticipates laser correction of presbyopia by removal of scleral tissue and movement of the ciliary muscle and zonules.

Alternatively, published independent claim 1 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299, taken alone or in view of either or both of *Lin* '679 and *Lin* '630. Laser photoablation of ocular surgery is well-known in the art, and selection of appropriate photoablation patterns to achieve correction of presbyopia through scleral expansion and accompanying movement of the ciliary muscle and zonule connections is a matter of routine and necessary experimentation. For example, *Lin* '630 and *Lin* '679 both disclose ocular laser

surgery techniques for removal (photoablation) of ocular tissue in predetermined patterns and areas using lasers. See, e.g., *Lin* '630, column 7, lines 52–58; *Lin* '679, Figures 4A–4E, 6A–6C and 7A–7B, column 13, lines 6–12. Skilled artisans would have been motivated to employ the techniques known in the art or disclosed by *Lin* '630 and/or *Lin* '679 to remove scleral tissue rather than corneal tissue by the teaching in *Schachar* '299 that such removal of scleral tissue will correct presbyopia.

Published claim 2 is anticipated under 35 U.S.C. § 102(b) by *Schachar* '299 or, alternatively, obvious under 35 U.S.C. § 103(a) over *Schachar* '299, taken alone or in view of either or both of *Lin* '630 or *Lin* '679. Published claim 2 recites that sub-conjunctival tissue fills the removed sclera tissue regions, increasing the flexibility of the sclera and producing movement of the ciliary body/zonules. Protester respectfully notes that such sub-conjunctival tissue filling of removed sclera tissue regions is disclosed in the subject application as an inherent result of removal of scleral tissue:

When portion [sic] of the scleral tissue 13 is removed by an ablative laser, this “gap” will be filled in by the sub-conjunctival tissue which is much more flexible than the original sclera tissue. This filled in sub-conjunctiva will allow the ciliary body 14 to contract or expand the zonular fiber 15 which is connected to the lens . . .

Pub. No. US 2001/0029363, ¶ 0032. No additional steps other than simply removing scleral tissue are taught in the subject application as being required for filling in removed scleral tissue regions with sub-conjunctival tissue. Accordingly, such a result is inherently achieved by

removal of scleral tissue as taught by *Schachar* '299, taken alone or in combination with either or both of *Lin* '630 and/or *Lin* '679.

Published claim 3 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 3 recites ablating scleral tissue in a radial pattern including at least three lines having a dimension of 0.1–1.0 mm by 2.0–5.0 mm. *Lin* '679 teaches ablating ocular tissue in radial patterns, with ablation areas formed using a laser having a spot size of 1 mm to ablate areas having a dimension of 2–9 mm. *Lin* '679, Figures 4C and 7A; column 11, lines 3–4; column 12, line 67 through column 13, line 1; column 13, lines 40–43; and column 14, line 48. This falls within the limitations of published claim 3.

Published claim 4 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 4 recites ablating two circles having a diameters of 10 mm and 18 mm. *Lin* '679 discloses such ablation of two circles with proportional diameters for corneal removal. *Lin*, '679, Figures 4D and 6B, column 11, line 5 and column 13, line 2.

Published claim 5 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 5 recites ablating scleral tissue in a pattern including at least three curved lines around the cornea, a feature shown in *Lin* '679. *Lin* '679, Figure 4D.

Published claim 6 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 6 recites ablating scleral tissue in a dotted ring pattern around the cornea, with each

dot having a diameter of about 0.1–1.0 mm. *Lin* '679 teaches forming such a dotted ring pattern using a laser having a spot size of 0.1–1.0 mm. *Lin* '679, Figure 4D, column 11, lines 21–24.

Published claim 7 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 7 recites generating the predetermined pattern using a scanning mechanism. *Lin* '679 discloses such a scanning mechanism 12. *Lin* '679, column 8, line 10.

Published claim 8 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299. Claim 1 recites that the predetermined pattern is generated by a fiber-coupled device. Such hand-held, fiber-coupled laser delivery systems and their use are well known in the fields of laser ocular surgery and related device design. See, e.g., *Lin* '679, column 11, line 39 (“manually operated fiber-tip”).

Published claim 9 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 9 recites that the predetermined pattern is generated by a translation device. *Lin* '679 discloses that the scanning system includes a motorized stage 20 for x and y movement. *Lin* '679, column 8, lines 7–34.

Published claim 10 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299. Claim 10 recites use of a mask in generating the predetermined pattern. Use of masks in laser ocular surgery are well-known in the art. See, e.g., *Lin* '679, column 2, line 9 (discussing prior patent teaching use of erodible mask).

Published claim 11 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 11 recites using an ultraviolet laser having a wavelength of 0.15-0.36 microns. *Lin* '679 teaches selecting an ultraviolet (UV) laser having a wavelength of 193–220 nm (0.193–0.220 microns). *Lin* '679, column 8, lines 8–9.

Published claim 12 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 12 recites employing a laser having a wavelength of 0.9-10.6 microns. *Lin* '679 teaches selecting numerous ultraviolet (UV), infrared (mid-IR), diode lasers, and other lasers having a wavelength within the recited range. *Lin* '679, column 4, line 45 through column 5, line 34.

Published claim 13 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299 in view of *Lin* '679. Claim 13 recites employing a solid state laser with a wavelength of 0.5–1.4 microns and pulse duration of 1 femtosecond (fs) to 1 nanosecond (ns). *Lin* '679 teaches using solid state lasers with wavelengths of 750–1100 nm (0.750–1.100 microns) and pulse durations of 0.05–10 picoseconds (ps). (Protester respectfully notes that a nanosecond is 10^{-9} seconds, a picosecond is 10^{-12} seconds, and a femtosecond is 10^{-15} seconds). *Lin* '679, column 9, lines 10–15.

Published claim 14 is obvious under 35 U.S.C. § 103(a) over *Schachar* '299. Claim 14 recites use of an optical fiber structure to deliver the laser to the eye. Such hand-held, fiber-

coupled laser delivery systems are well known in the fields of laser ocular surgery and related device design. See, e.g., *Lin* '679, column 11, line 39 ("manually operated fiber-tip").

Published claims 15–17 are obvious under 35 U.S.C. § 103(a) over *Schachar* '299. These claims each recite that the conjunctiva is either opened or not opened to remove scleral tissue. Those skilled in the art, in applying the teaching of *Schachar* '299 to removal of scleral tissue, would readily determine whether to open the conjunctiva depending upon the particular process employed.

Published claims 1–17 are invalid under 35 U.S.C. § 101 for double patenting over U.S. Patent No. ^{'082}~~6,263,879~~ to *Lin*. *Lin* '082 discloses and claims in claims 3–15 a method of correcting presbyopia by laser ablation of scleral tissue to increase accommodation as recited in claim 1 of the subject application. The sub-conjunctival tissue filling of removed scleral regions as recited in published claim 2 of the subject application inherently results from performance of the process disclosed and claimed in *Lin* '082. *Lin* '082 also discloses and/or claims the various limitations of published claims 3–9 and 11–14 as follows:

- 3: spot sizes of 0.1–1.0 mm used to form radial lines of 2.5–3.5 mm length – *Lin* '082, column 9, lines 22–23 and 48 and claims 13–15;
- 4: ablation in two circles having diameters of 10 and 12 mm – *Lin* '082, Figure 4C, column 5, lines 13–20;

- 5: ablation pattern including at least three curved lines around the cornea outside the limbus – *Lin* '082, Figures 4B–4C, column 5, lines 12–16;
- 6: ablation pattern comprising a dotted ring pattern with a dot size of 0.1–0.5 mm in diameter – *Lin* '082, Figure 4D, column 5, lines 15–19;
- 7: scanning device 4 utilized to generate ablation pattern – *Lin* '082, column 7, line 41;
- 8: fiber-coupled laser delivery device – *Lin* '082, column 9, lines 60–61 and claim 12;
- 9: computer controlled scanning mirrors which move in x and y directions – *Lin* '082, column 9, lines 55–57 and claim 14;
- 11: ultraviolet laser with wavelength of 0.190–0.220 microns – *Lin* '082, column 8, lines 45–46 and claim 10;
- 12: infrared laser with wavelength of 2.7–3.2 microns – *Lin* '082, column 8, lines 44–45 and claim 5;
- 13: solid state lasers and pulse durations of 1 ns – *Lin* '082, column 8, lines 47–48, column 9, line 1 and claim 5; and
- 14: movement of fiber-coupled device to form ablation patterns – *Lin* '082, column 9, lines 60–61.

Additionally, the limitation of published claim 10 (use of mask in ablating ocular tissue) is well-known in the art, and the limitations of published claims 15–17 (either opening or not opening

the conjunctiva before ablating the sclera tissue) are inherent and required in use of photoablation of scleral tissue, such that the limitations of claims 10 and 15–17 are obvious.

Additionally, published claims 3–9 and 11–14 are anticipated under 35 U.S.C. § 102(e) by *Lin* '879 for the reasons described above. Similarly, claims 1–17 are obvious under 35 U.S.C. § 103(a) over *Lin* '879, taken alone or in combination with any of *Schachar* '299, *Lin* '630 and/or *Lin* '679, for the reasons described above.

If any issues arise, or if the Examiner has any questions, Protester respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@novakov.com.

ATTORNEY DOCKET NO. PRES06-00219
U.S. APPLICATION SERIAL NO. 09/820,832
PROTEST

The Commissioner is hereby authorized to charge any fees required in connection with this communication or credit any overpayment to Deposit Account No. 50-0208.

Respectfully submitted,

NOVAKOV DAVIS & MUNCK, P.C.

Date: Jan. 3, 2002



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PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
PRES06-00219SERIAL NO.
09/820,830LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)APPLICANT
J.T. LinFILING DATE
March 30, 2001

GROUP

U. S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA	5,144,630	09/01/1992	Lin	372	22	07/29/1991
	AB	5,489,299	02/06/1996	Schachar	623	4	10/22/1993
	AC	5,520,679	05/28/1996	Lin	606	5	03/25/1994
	AD	6,258,082	07/10/2001	Lin	606	5	05/03/1999
	AE	US 2001/0029363	10/11/2001	Lin	606	5	03/30/2001

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line if not in conformance and not considered. Include copy of this form with next communication to applicant.

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